activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to the identified needs.

Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: (1) Structured and qualitative interviewing for surveillance, research, interventions and material development, (2) cognitive interviewing for development of specific data collection instruments, (3) methodological research (4) usability testing of technology-based instruments and materials, (5) field testing of new methodologies and materials, (6) investigation of mental models for health decision-making, to inform health communication messages, and (7) organizational needs assessments to support development of capacity. Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements.

In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation of respondents is voluntary. The total burden hours are 55,820. There is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response
General public	Screener Att6	68,208	1	10/60
Healthcare providers	Screener Att6	29,232	1	10/60
General public	Consent Forms Att9	34,104	1	5/60
Healthcare providers	Consent Forms Att9	14,616	1	5/60
General public	Individual interview Att4	5,544	1	1
Healthcare providers	Individual Interview Att4	2,376	1	1
General Public	Focus Group Interview Att7	3,360	1	2
Healthcare providers	Focus Group Interview Att7	1,440	1	2
General public	Survey of Individual Att5	25,200	1	30/60
Healthcare providers	Survey of Individual Att5	10,800	1	30/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–27431 Filed 10–27–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Project: Implementation Plan Guidance for the Tribal Maternal, Infant, and Early Childhood Home Visiting Grant Program.

Title: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Needs Assessment and Implementation Plan.

OMB No.: 0970–0389.

Description: Social Security Act, Title V, Section 511 (42 U.S.C. 711), as added by § 2951 of the Patient Protection and Affordable Care Act (Pub. L. 111–148*),* created the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV) and authorized the Secretary of HHS (in Section 511(h)(2)(A)) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation (authorized in Section 511(j)) for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions (authorized in Section 511(c)), and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The Administration for Children and Families, Office of Child Care and Office of the Deputy Assistant Secretary for Early Childhood Development, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, plans to awarded grants for the Tribal Maternal, Infant, and Early Childhood Home Visiting Program (Tribal Home Visiting). The Tribal Home Visiting grant awards will support 5-year cooperative agreements to conduct community needs assessments, plan for and implement high-quality, culturally-relevant, evidence-based home visiting programs in at-risk Tribal communities, and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

In Year 1 of the cooperative agreement, grantees must (1) conduct a comprehensive community needs and readiness assessment and (2) develop a plan to respond to identified needs. Specifically, grantees will be required to conduct or update a needs and readiness assessment, and develop an implementation plan to respond to those needs, including a plan for performance measurement and CQI and participating in or conducting rigorous evaluation activities. Grantees will be expected to submit the needs assessment and implementation plan within 10 months of the Year 1 award date.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Year 1 Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal Maternal, Infant, and Early Childhood Home Visiting Program Needs Assessment and Plan for Responding to Identified Needs	25	1	100	2,500
Estimated Total Annual Burden Hours				2,500

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–27416 Filed 10–27–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0477]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions Reports and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on investigational device exemptions reports and records.

DATES: Submit either electronic or written comments on the collection of information by December 28, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–N–0477 for Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions Reports and Records. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the